



Functional Foods and Dietetic foods

6 November 2008



Seminar on Functional food and innovative research
A key to better health

“Functional foods” under EU Law

- Not defined as a specific category
- Not regulated as such

Therefore the term may be used for or attributed to many different foods

“Functional foods”

Foods that may claim a nutritional or health benefit

They are subject to:

- EU horizontal rules applicable to foods in general
- EU specific rules applicable
- National specific rules of Member States in the absence of relevant EU rules

“Functional foods”

Foods that may claim a nutritional or health benefit

- Novel foods (Regulation 258/1997)
- Fortified foods (Regulation 1925/2006)
- Food supplements (Directive 2002/46/EC)
- Dietetic foods (Directive 89/398/EC)

Novel Food

Regulation (EC) No. 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients

- Food and food ingredients that are 'novel' to the European market require pre-marketing authorisation
- Directly applicable throughout the European Union

Fortified foods

Key provisions of Regulation 1925/2006

- Conditions for the addition of vitamins and minerals to foods
- List of vitamins and minerals and their specific chemical forms
- Criteria for setting maximum levels
- Procedure for dealing with certain other substances



Food supplements

Definition

“food supplements” means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities”

Food supplements

Key provisions of Directive 2002/46/EC

Scope

- Wide range of nutrients and other ingredients that might be present in food supplements including, but not limited to, vitamins, minerals, amino acids, essential fatty acids, fibre and various plants and herbal extracts
- The directive lays down compositional rules only for vitamins and minerals used as ingredients of food supplements

Dietetic Foods

Definition

■ What are they ?

Foods for particular nutritional uses (or dietetic foods) are specially manufactured products intended to satisfy the particular nutritional requirements of specific categories of the population

Council Directive on dietetic foods (89/398/EEC)
“the framework Directive”

Dietetic Foods

Specific Commission Directives

- **Infant formulae**
(Commission Directive 2006/141/EC; Council Directive 95/52/EEC)
- **Cereal-based foods and baby foods**
(Commission Directive 2006/125/EC)
- **Energy-restricted diets for weight reduction**
(Commission Directive 96/8/EC; Commission Directive 2007/29/EC)
- **Dietary food for special medical purposes**
(Commission Directive 1999/21/EC)
- **Substances for nutritional uses**
(Commission Directive 2001/15/EC)

Dietetic Foods

Categories

Foods submitted to a notification procedure

- Gluten-free foods for coeliac people
- Lactose-free foods
- Growing up milk for children
- Foods for pregnant women
- Etc.



Foods suitable for people intolerant to gluten

What is coeliac disease?

People with coeliac disease are a specific group of the population suffering from a permanent intolerance to gluten which is a protein naturally present in some cereal grains

Why do we need to harmonise?

- Increasing number of foods described as 'gluten-free' (57% of the notified products)
- Conditions for the use of terms related to the absence of gluten should be the same in all EU MS
- A revised Codex standard was adopted the 1 July 2008

Which are the gluten containing cereal grains?

- Wheat (i.e. all Triticum species, such as durum wheat, spelt, and kamut)
 - rye
 - barley
- 

What about oats?

- A long running debate about the toxicity of oats for coeliacs
- No consensus on the oat prolamin “avenin”
- Major concern is the contamination of oats by other gluten containing cereals
- Research data suggest that the majority of individuals with coeliac disease can tolerate a limited amount of oats that are free of gluten from wheat, rye and barley



Basic principles

- Different people may tolerate different amounts of gluten within a restricted range
- Important to have a variety of food suitable for coeliac people appropriate to their needs and for their level of sensitivity
- Foods for normal consumption when suitable for coeliac people should have the possibility to indicate it (Article 2.3 of Dir 89/398/EEC and Recital 22 of Regulation 1924/2006)



Draft Commission Regulation concerning the composition and labelling of foods suitable for people intolerant to gluten

Purpose and scope

- Purpose: rules for the use of terms indicating the absence of gluten
- Scope:
 - dietetic foods specially manufactured for people intolerant to gluten
 - dietetic foods for other purposes
 - foods for normal consumption

Dietetic foods and oats

- If dietetic foods especially processed for gluten intolerant people contain oats, only oats which have been specially produced, prepared and processed in order to avoid contamination by wheat, rye, barley, with a gluten content no greater than 20 mg/kg in total* may be used

***based on the food as sold to the final consumer**

Dietetic foods specially manufactured for people intolerant to gluten

- shall bear either 'very low gluten' or 'gluten-free' in proximity to the name under which the food is sold
- If these foods contain oats, pure oats shall be used
 - if dietetic food consisting of or containing one or more ingredients made from wheat, rye and barley specially processed **to remove** gluten
 - max level of gluten: 100 mg/kg* and shall bear 'very low gluten'
 - if level of gluten ≤ 20 mg/kg* may bear 'gluten-free'

*in the food as sold to the final consumer

Dietetic foods specially manufactured for people intolerant to gluten

- if dietetic food consisting of or containing one or more ingredients **which substitute** wheat, rye and barley
- max level of gluten: 20 mg/kg*
- shall bear 'gluten-free'

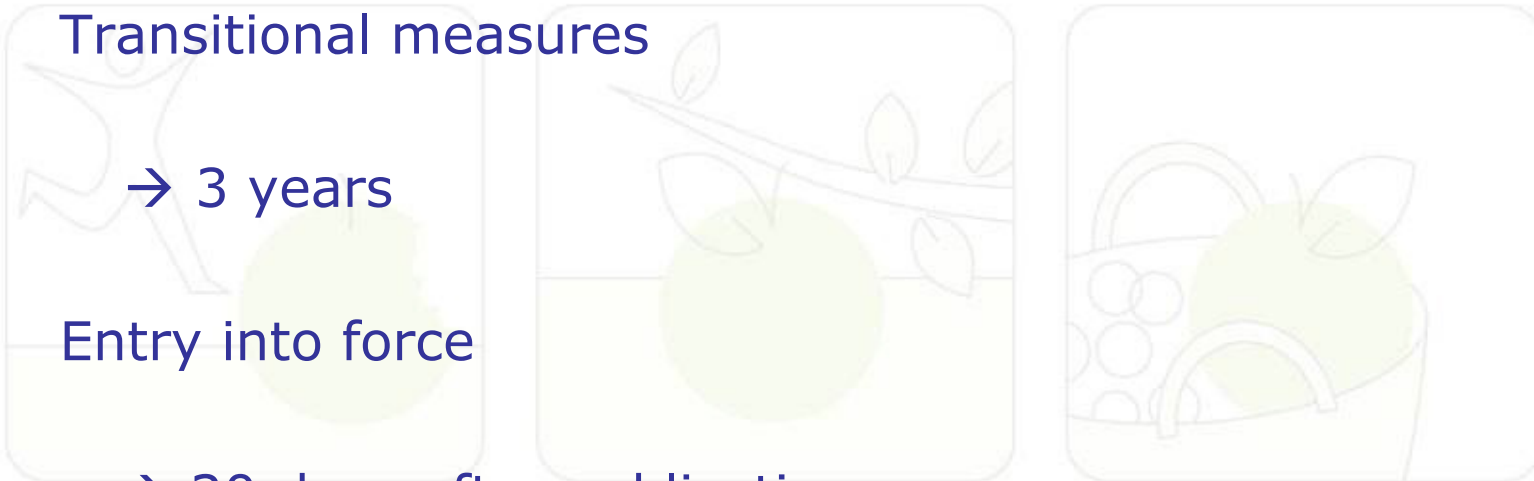
***in the food as sold to the final consumer**

Other dietetic foods and foods for normal consumption

- 
- max level of gluten: 20 mg/kg
 - may bear 'gluten-free'
 - shall not bear 'very low gluten'
 - shall not be misleading to consumer

Application

- Transitional measures
 - 3 years
- Entry into force
 - 20 days after publication
(foreseen: February 2009)





Foods suitable for people
intolerant to gluten



Merci pour votre attention!